

### **REMARKS**

Please enter for examination new claims 51-53 as submitted herein.

Applicants respectfully request reconsideration of the above-identified application. Claims 1-37 remain pending in the application.

#### **Rejection For Non-Statutory Double Patenting**

Claims 7 and 14 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of either of pending U.S. Patent Applications Serial Nos. 10/463,908 or 10/351,196.

Applicant notes the rejection of Claims 7 and 14 for non-statutory double-patenting and will consider the filing of a terminal disclaimer once the scope of allowed claims of the instant application and of the relevant Claim 2 of U.S. Patent Applications Serial Nos. 10/463,908 or 10/351,196 are known.

#### **Objection to Claims due to Informalities**

Claims 30-34, 36 and 37 are objected to as encompassing non-elected subject matter.

The Examiner stated that "the claim will therefore be examined only to the extent that it reads on an isolated eukaryotic cell or a cell in culture. The claim should be amended such that it no longer encompasses a cell in vivo."

Claims 30-34, 36 and 37 are herein amended to read on an isolated eukaryotic cell, and its progeny, in culture. Applicants, therefore, respectfully request that this objection be withdrawn.

**Rejection Under 35 U.S.C. § 101**

Claims 30 and 35-37 are rejected under 35 U.S.C. § 101. The Examiner stated that the claimed invention is directed to non-statutory subject matter, as the claims read on a transgenic animal “in such a way as not to exclude a transgenic human”.

Claims 30 and 35-37 are herein amended to clearly indicate that the host cell and its progeny are “isolated”, and the cell, and its progeny, is a cultured cell, thereby rendering this rejection moot and should be withdrawn.

**Rejection Under 35 U.S.C. § 112, first paragraph**

Claims 1-37 are rejected under 35 U.S.C. § 112, first paragraph (written description)

The Examiner states at pages 5-6 of the Office Action that “the claims also encompass variants of the chicken promoter region set forth as SEQ ID NO: 26 including those ovomucoid gene expression control regions found in turkey, duck, goose, quail, pheasant, ratite, ornamental bird or feral bird ovomucoid gene expression control region. Thus, the claims appear to be generic to any ovomucoid gene expression control region found within a wide variety of avian species.”

Claims 2, 3, 8, 9, 19 and 20 are herein canceled. This rejection is, therefore, now rendered moot and should be withdrawn.

The Examiner further states at page 7 of the Office action that “Claims 1-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid comprising the sequence set forth as SEQ ID NO: 26, does not reasonably provide enablement for any variant thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.”

The Examiner further states that “there are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue.”

Claims 1, 10 and 21 are herein amended to delete the phrase “or degenerate variants thereof.”

Applicants appreciate the recommendation by the Examiner that Claims 1-37 are enabled as required under 35 U.S.C. § 112, first paragraph, with respect to using the chicken ovomucoid gene expression regulatory region as given in SEQ ID NO: 26 to regulate the expression of heterologous polynucleotides. Applicants, therefore, respectfully request that this rejection be withdrawn.

**Rejection Under 35 U.S.C. § 112, second paragraph**

Claims 1-6, 10, 12, 21, 23 and 27-29 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventors regard as the invention.

The Examiner states that Claims 1, 10 and 21 are indefinite in being directed to a “degenerate variant” of SEQ ID NO: 26. Claims 1, 10 and 21 are herein amended to delete the reference to “degenerate variant,” so that this rejection with respect to Claims 1, 10 and 21 is now rendered moot and should be withdrawn.

The Examiner states that Claims 12, 23, 28 and 29 are indefinite because they recite limitations as derivatives of some starting material. Claims 12, 23, 28 and 29 are herein amended to substitute “isolated from” for “derived from” so that this rejection with respect to Claims 12, 23, 28 and 29 is rendered moot and should be withdrawn.

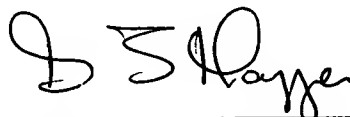
The Examiner states that Claim 23 is indefinite in reciting "the polyadenylation signal." Claim 23 is herein amended to correctly depend on Claim 22, thereby providing antecedent basis so that this rejection with respect to Claim 23 is now rendered moot and should be withdrawn.

The Examiner states that Claim 27, and Claims 28 and 29 dependent therefrom, are rejected for omitting essential elements. Claim 27 is herein amended to include a nucleic acid encoding the heterologous polypeptide operably linked to the ovomucoid gene expression control region, so that this rejection with respect to Claims 27-29 is now rendered moot and should be withdrawn.

### CONCLUSION

The application is now in condition for allowance, and prompt notification thereof is earnestly solicited. If it is believed that issues remain unresolved, the Examiner is invited to contact the undersigned.

Respectfully submitted,



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